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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/891,881 | 06/26/2001 | John J. Voorhees | 1718-010A | 9061 |

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EXAMINER
WINSTON, RANDALL O

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1654 | |

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,881

Applicant(s)

VOORHEES ET AL.

Examiner

Randall Winston

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/03/2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on 02/03/2005.

The rejection made under 35 U.S.C. 112 1st has been overcome by Applicant's amendment of 02/03/2005.

The rejections made under 35 U.S.C. 102(b) and (e) and 35 U.S.C. 103(a) have been overcome by applicant's election of species of the brominated quinazolines for examination in applicant's notice of non-compliant amendment response filed on 02/03/2005.

Amended claims 8-16 and new claims 17-20 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 as amended stands rejected under 35 U.S.C. 102(e) as being anticipated by Uckun et al. (US 6,258,820).

Applicant claims a composition for reducing the induction of MMPs in human skin due to exposure of the skin to UV radiation comprising an effective amount of an EGF-R

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protein tyrosine kinase inhibitor (i.e. brominated quinazoline) admixed in a dermatologically suitable carrier.

Uckun et al. anticipate the claimed invention (see, e.g., column 7 lines 1-7 and example 2), because Uckun et al. teach the topical administration of an EGR-R protein tyrosine kinase inhibitor (i.e. quinazoline compounds such as brominated quinazoline) admixed in a dermatologically suitable carrier whereas the claimed quinazoline compound would also inherently inhibit UV-inducement of MMPs in human skin when administered topically to the skin to protect the skin from UV radiation. Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-16 as amended stands rejected and new claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uckun et al. in view of Wei (US 5824702), Kelly et al. (US 6,455032), Moldenhauer et al. (US 5,985,296), Rhodes (US 4,082,679) and Fisher et al. (US 6,130,254).

Applicant claims composition to inhibit UV-inducement of MMPs in human skin due to exposure of the skin to UV radiation comprising an EGR-R protein tyrosine kinase inhibitor, an antioxidant, a retinol, a P-450-inhibitor, a UVA blocker and UVB blocker admixed in a dermatological suitable carrier.

Uckun et al. teach the topical administration of an EGR-R protein tyrosine kinase inhibitor (i.e. quinazoline compounds such as brominated quinazoline) admixed in a dermatologically suitable carrier whereas the claimed quinazoline compound would also intrinsically inhibit UV-inducement of MMPs in human skin when administered topically to the skin to protect the skin from UV radiation. Uckun et al. do not teach the inclusion admixed within a composition of an antioxidant, retinol, a P-450 inhibitor, a UVA blocker and a UVB blocker to protect the skin from UV radiation.

Both Wei and Kelly et al. teach an antioxidant (i.e. genistein) applied to the skin to intrinsically to protect the skin from UV radiation when administered to the skin.

Moldenhauer et al. beneficially teach (see, e.g. column 1 lines 31-40) retinol as an active ingredient to protect the skin from UV radiation.

Rhodes beneficially teaches (see, e.g. column 1 lines 66-68 and column 2 lines 1-7) a P-450 inhibitor (i.e. triazole) as an active ingredient to protect the skin from UV radiation.

Fisher et al. beneficially teach (see, e.g., column 3 lines 33-47) a UVA blocker and a UVB blocker as active ingredients to protect the skin from UV radiation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Uckun et al. to include the beneficial teachings of Wei and/or Kelly et al., Moldenhauer et al., Rhodes and Fisher et al. for the creation of an improved synergistic claimed composition to protect the skin from UV radiation whereas the claimed synergistic composition would also intrinsically inhibit UV-inducement of MMPs in human skin when administered. The adjustment of other

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conventional working conditions (i.e. screening the brominated quinazoline for its ability to diminish activation of EGFR), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
4-18-05

**SUSAN COE
PRIMARY EXAMINER**